DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
New Orleans District
Nashville Branch
297 Plus Park Blvd.
Nashville, TN 37217

M3490n

February 9, 2000

Rec'd 2/28/00 JED

CERTIFIED - RETURN RECEIPT REQUESTED

Mr. Charles J. Steer
1040 Banks Levy Road
Cottage Grove, TN 38224

WARNING LETTER - 00-NSV-07

Dear Mr. Steer:

An investigation at your dairy farm located at Cottage Grove, Tennessee by our investigators on December 16, 1999 confirmed that you offered animals for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about July 23, 1999 you shipped in interstate commerce a cow identified by U.S. Department of Agriculture (USDA) sample number 375043 for slaughter as human food at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 14.0 parts per million (PPM), 30.0 PPM, and 8.3 PPM oxytetracycline in the liver, kidney and muscle, respectively. A tolerance of 2 PPM in muscle, 6 PPM in liver, and 12 PPM in kidney tissue has been established for residues of oxytetracycline in the edible tissue of nonlactating dairy cattle (Title 21, Code of Federal Regulations, 556.500). We understand that this cow calved on or about July 20, 1999.

On or about August 27, 1999 you also shipped in interstate commerce a cow identified by USDA sample number 375047 for slaughter as human food at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 1.7 PPM gentamicin in the kidney.

The presence of oxytetracycline or any residue of gentamicin in edible tissues from these animals causes the food to be adulterated.

Our investigation also found that you hold animals under conditions that are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those species and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

You are adulterating the drugs oxytetracycline and gentamicin within the meaning of Section 501(a)(5) of the Act when you fail to use the drugs in conformance with their approved labeling. Your use of these drugs in cows for which they are not approved and without following labeled withdrawal periods causes the drugs to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

You should notify this office in writing within 15 working days of the steps you have taken to bring your farm into compliance with the law. Your response should include each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,

Alonza E. Cruse
Acting Director
New Orleans District

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